COWELL MEDI
Bio Plant System

http://www.cowellmedi.com

Head office
ADDRESS : Dong-ju Bldg 2F 45-3, Kaya-1Dong, BusanJin-Gu, Busan, Korea
TEL : 82-51-644-2028, 896-2877, 896-2553 FAX : 82-51-896-2554
Factory
ADDRESS : 565-12, Gwaebeob-Dong, Sasang-Gu, Busan, Korea
TEL : 82-51-314-2028, 316-2027 FAX : 82-51-314-2026

SEP - 8 2004

Section 5
510(k) Summary per 21 CFR 807.92

K# 041655

Date: 19 January 2004

US Agent / Contact:
RA/QA International, L.L.C. (Mr. Martin Leighton)
161 Little Bay Road
Newington, NH 03801
Tel. 603 373 0260

Manufacturer:
Cowell Medi Co., Ltd.
Dongju Bldg. 2F., 45-3, Gaya 1 Dong, Busanjin-Gu, Busan, 614-800, Korea
Tel: 82-51-896-2877 / 82-51-314-2028
Fax.: 82-51-896-2554 / 82-51-314-2026
Contact Point: Mr. Soo-Hong Kim

Proprietary Name: BioPlant System

Common Name: Endosseous Dental Implant

Classification Name: Endosseous implants, surgical components, and prosthetic attachments

Predicate Devices: Branemark System - Nobel Biocare: K925777, K925779, K961728, K971706, K974150 K992937, K993595, K022562 and 3i Restorative Implant Systems - Implant Innovations Inc.: K983347, K965077, K934126, K935544, K022009, K022113

Device Description:
The Bio Plant System includes a variety of types and sizes of precision-machined self-tapping root-form implants, abutments and accessory fixtures manufactured from biocompatible, commercially pure (CP) titanium. Some abutments and screws (accessory fixtures) are manufactured from biocompatible, wrought titanium or gold alloy. The implants are self-tapping screw-type design with hex-lock features and either smooth (bright) or textured (abrasive blasted) surface finish. Implants range from 3.3 mm to 6.0 mm thread diameter and from 7mm to 18 mm in length. The implants are intended to be surgically inserted into the upper and/or lower jawbone and serve as a substitute or replacement tooth root while providing a stable foundation for restorations. Drill sequences, drills and insertion instruments, for the respective implants, abutments and accessory fixtures are specified and available.

Indication for Use:
BioPlant Systems refer to sets of root form endosseous dental implants and compatible implant abutment systems. BioPlant Systems are designed for use in dental implant surgery and are intended to be used in a manor in which they (the implants) integrate with the bone (osseointegration). The BioPlant abutment systems include various abutments designed to enable the implant process from healing thru final restoration. Clinical studies have demonstrated that, when surgically implanted under controlled conditions, a successfully osseointegrated implant will achieve a firm and direct connection between the living bone and surface of the titanium implant. BioPlant implants are for single or two-stage surgical procedures. Bio Plant Systems are intended for immediate placement in partially or fully edentulous mandibles and maxillae (type I or II bone), in support of single or multiple-unit restorations including; cement retained, screw retained, or over-denture restorations, and terminal or intermediate abutment support for fixed bridgework. Multiple tooth applications may be splinted with a bar.

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Table, 510(k) Summary per 21 CFR 807.92: Predicate Device(s) Comparison

ATTRIBUTE / CHARACTERISTIC	COWELL MEDI BIOPLANT SYSTEM (Submitted Product)	LEGALLY MARKETED PREDICATE DEVICES OF Nobel Biocare USA & AB	LEGALLY MARKETED PREDICATE DEVICES OF Implant Innovations, Inc. (*3i*)
"K" numbers	K_____	K925777, K925779, K961728, K971706, K974140 K992937, K993595, K022562	K983347, K965077, K934126, K935544, K022009, K022113
Proprietary Name	BioPlant System	Brånemark System®	*3i* Restorative Dental Implant Systems
CFR Section	872.3640	SAME	SAME
Pro-code	DZE & NHA	SAME	SAME
Classification name	Endosseous Dental Implant and Abutment Device	SAME	SAME
Intended / Indications for use:	BioPlant Systems refer to sets of root form endosseous dental implants and compatible implant abutment systems. BioPlant Systems are designed for use in dental implant surgery and are intended to be used in a manor in which they (the implants) integrate with the bone (osseointegration). The BioPlant abutment systems include various abutments designed to enable the implant process from healing thru final restoration. Clinical studies have demonstrated that, when surgically implanted under controlled conditions, a successfully osseointegrated implant will achieve a firm and direct connection between the living bone and surface of the titanium implant. BioPlant	(Functionally the same) Brånemark System implants are for single-stage or two-stage surgical procedures and cement or screw retained restorations. The Brånemark System implants are intended for immediate placement and function on single tooth and or multiple tooth applications recognizing sufficient bone stability (type I or II bone) and appropriate occlusal loading, to restore chewing functions. Multiple applications may be splinted with a bar. The Brånemark Abutments System is a set of cemented or screw retained preparable abutments which are secured to an endosseous implant and is intended to function as an anchor to which prosthetic devices, such as artificial	(Functionally the same) *3i* Dental Implant Systems are indicated for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment to restore a patients chewing function. Abutments and accessories are indicated for use in surgical and restorative applications when placing dental implants.

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Continued: **Intended / Indications for use:**	implants are for single or two-stage surgical procedures. Bio Plant Systems are intended for immediate placement in partially or fully edentulous mandibles and maxillae (type I or II bone), in support of single or multiple-unit restorations including: cement retained, screw retained, or over-denture restorations, and terminal or intermediate abutment support for fixed bridgework. Multiple tooth applications may be splinted with a bar.	teeth, may be attached using dental cement to restore a patient's chewing function.	
Design –(Implants)	Threaded, self tapping, external hex, root-form	SAME	SAME
Diameter–(Implants)	3.3 – 6.0 mm	3.3 – 5.0 mm	3.25 – 6.0mm
Length –(Implants)	7.0- 18 mm	SAME	SAME
Material –(Implants)	Commercially pure (CP) titanium (Ti)	SAME	SAME
Coating–(Implants)	Non-coated	Non-coated and Coated (HA)	Non-coated and Coated (HA)
Surface Finish (Implants)	Machined or roughened / textured (abrasive blasted). If roughened, the transmucosal part maintains a smooth machined finish to allow for the attachment of epithelial tissue.	EQUIVALENT: Machined or roughened /textured via proprietary roughening method. If roughened, the transmucosal part maintains a smooth machined finish to allow for the attachment of epithelial tissue.	EQUIVALENT: Machined or roughened / textured via proprietary roughening method. If roughened, the transmucosal part maintains a smooth machined finish to allow for the attachment of epithelial tissue.

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Design –(Abutments)	Abutments (straight, no angle): healing, cemented and non-cemented / screw attached, Miniscone, Esthetic one, temporary and UCLA type, with associated cylinder and coping screws.	EQUIVALENT: but also include angled and universal abutments	EQUIVALENT: but also include angled and universal abutments
Materials–(Abutments)	CP Ti, Ti alloy, or gold alloy	CP Ti, Ti alloy, gold alloy and ceramic	CP Ti, Ti alloy, gold alloy and plastic
Materials–(screws)	CP Ti, Ti alloy, or gold alloy	SAME	SAME
Color additives –(Implants & Abutments)	There are no color additives used in any of the materials of the components of the device.	SAME	SAME
Accessories available – drills drivers:	point, twist, tap, pilot, countersink, hand-driver, machine driver, mount driver	EQUIVALENT	EQUIVALENT
Provided Sterile? – (Implants & Abutments)	YES	YES	YES
Sterilization Method(s)	Irradiation, SAL 10^{-6}	Various Methods	SAME
Packaging – (Implants)	Polymeric ampul in peel-open blister pack	Glass ampul in peel-open blister pack	Heat sealed peel-open nylon pouch
Packaging – (Abutments / screws)	Various methods	EQUIVALENT	EQUIVALENT
Contraindications (from instructions for use (IFU) package insert labeling)	Bio Plant System implants should not be placed in patients where the retaining jawbone is too diminished to provide adequate width or height to surround the implant. Failure to	FUNCTIOALLY EQUIVALENT: (from IFU) Pre-operative patient evaluation is necessary to determine any factors which put the patient risk from the implant placement procedure itself of	FUNCTIOALLY EQUIVALENT: (from 510(k) Summary) Implants should not be used in cases where the remaining jawbone is too diminished to provide adequate width or height to surround

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Continued: **Contraindications (from instructions for use (IFU) package insert labeling)**	osseointegration or subsequent loss of osseointegration may occur in cases where there is insufficient available bone, poor bone quality, poor oral hygiene, heavy smoking or tobacco abuse, or medical conditions such as blood disorders or uncontrolled diabetes. Contraindications associated with elective surgery should be observed. Possible contraindications: Chronic bleeding problem; psychological impairment; metabolic bone or connective tissue diseases; treatment with corticosteroids; certain cardiac and vascular diseases; tobacco usage diabetes (uncontrolled); treatment with chemotherapeutic agent; chronic renal disease; poor patient oral hygiene; bruxing; alcoholism. Temporary contraindications: Systemic infection; local oral or respiratory infection. Anatomical or pathological contraindications: Insufficient alveolar bone width and height to surround the implant with at least one millimeter of bone, both buccally and lingually to the most superior aspect of the implant	factors that may effect healing capacities of either the bone or associated soft tissue. Dental implants should not be used in patients who are unfit medically for a general oral surgical procedure. For patients who have local of systemic factors which could be expected to interfere with the healing process of either bone or soft tissue (e.g. connective tissue disorders, steroid therapy, infections in bone, cigarette smoking) the potential benefits and risks of treatment need to be carefully evaluated. In addition, the patients need to have an adequate volume of residual bone for placing sufficient size and numbers of implants to support the anticipated functional loads the patient will subject these implants to. Insufficient size or numbers of implants to support biomechanical loads or undesirable positioning of the implants can lead to mechanical failure including fatigue fracture of implants, prosthetic screws or abutment screws. Implant placement and prosthetic design must accommodate individual patient conditions such	the implant. Lack of osseointegration or subsequent implant failure may occur in cases where there is insufficient available bone or poor bone quality, poor oral hygiene, heavy smoking or tobacco abuse, or medical conditions such as blood disorders, infection(s), vascular impairment at surgical site, uncontrolled diabetes, heavy smoking or tobacco abuse, drug or alcohol abuse, chronic high dose steroid therapy, medical conditions such as blood clotting disorders, current or ongoing anticoagulant therapy, metabolic bone disease or other metabolic or systemic disorders which may adversely affect bone or wound healing or cases in which the available bone is too diminished to provide adequate width or height to adequately hold implants and restorative appliances.

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Continued: **Contraindications (from instructions for use (IFU) package insert labeling)**	placement would encroach on the mandibular canal; malignancies.	as bruxism or unfavorable jaw relationships to reduce the risk of overload or fatigue failure. and treatment is contraindicated if adequate accommodation cannot be accomplished. If inadequate bone volume is present augmentation procedures can be considered. Please consult appropriate surgical and restorative manuals and textbooks for information on treatment planning and medical evaluation.	
Precautions and Warnings (from instructions for use (IFU) package insert labeling)	Content of the precaution and warning sections for the (IFU) package insert generally refer to the need for practitioners to lean and employ proper technique, to appropriately acknowledge contraindications. not to modify any components or instrumentation. to utilized only components and instrumentation designated by the manufacturer and that failure to observe cautions and warnings could result in failure of the procedure and or harm to the patient.	FUNCTIOALLY EQUIVALENT to precautions and warnings provided in (IFU) package insert labeling.	FUNCTIOALLY EQUIVALENT: Actual IFU labeling was unavailable at the time of this 510(k) submission however *3i's* on-line surgical manual provides functionally equivalent information.
Non-clinical testing performed:	Though the Cowell Medi implant and abutment designs and technology characteristics are not	510(k) summaries available for Brånemark System® suggest that similar testing was	510(k) summaries available for *3i* Dental Implant Systems suggest that similar testing was

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Continued: **Non-clinical testing performed:**	significantly different from the predicate devices to which substantial equivalency is sought. mechanical fatigue testing under shear force with a 25kg load. and static shear testing was performed to establish the mechanical properties of the BioPlant System and to confirm fixture/implant-abutment compatibility. BioPlant System production unit implant-abutment system samples. considered physically representative of the design most prone to worst-case mechanical loading following implantation. were subjected to testing per part 5 of ISO 14801. Assembled implant-abutment samples were subjected to 5 million cycles (2-14 Hz) under shear forces with 25kg loads applied 30° off the center axis of the implant-abutment system. All samples survived. Assembled implant-abutment samples were also subjected to static shear testing to establish the yield point of the fixture and abutment fixed with a screw. All samples exhibited acceptable yield points and no fractures or crack occurred prior to yield. Protocols and results are provided	performed and similar outcomes achieved.	performed and similar outcomes achieved.

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Continued: **Non-clinical testing performed:**	in section 13 of this submission.		
Clinical data / performance testing:	Abundant, significant, peer reviewed documentation supporting the successful clinical performance of root-form endosseous dental implants and abutment systems exists. The Cowell Medi implants and abutment systems (BioPlant Systems) that are the subject of this 510(k) submission are substantially equivalent in design, technology and labeling to many of the devices identified in the aforementioned documentation, including but not limited to the legally marketed predicate devices identified in this submission. Cowell Medi perceives the adequacy of such existing documentation substantiates the exclusion of both animal and human clinical studies protocols or data.		

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Additional Information			
Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Abutments; Draft Guidance for Industry and FDA	510(k) for Cowell Medi BioPlant System submitted in accordance with content of Special Controls Guidance Document: Root-form Endosseous Dental Implants		

Conclusion: **Based on a review of available 510(k) summaries for product codes DZE (implants) and NHA (abutments), and a review of available labeling for same, the Cowell Medi BioPlant System of root-form endosseous dental implants, abutments and accessories are substantially equivalent[1] to like devices legally marketed by Nobel Biocare (Brånemark System®) and *3i* Implant Innovations, Inc. (*3i* Restorative Dental Implant Systems)**

----------End----------

510(k) Summary per 21 CFR 807.92

[1] Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to refer to whether ther product can be lawfully marketed without a pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. (Establishment Registration and Pre-market Notification Procedure, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No, 76N-0355))

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2004

Cowell Medi, Company Limited
C/O Mr. Martin J. Leighton
Regulatory Affairs Quality Assurance, International, LLC
161 Little Bay Road
Newington, New Hampshire 03801

Re: K041655
Trade/Device Name: BioPlant System (Implants and Abutments)
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: April 16, 2004
Received: June 18, 2004

Dear Mr. Leighton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

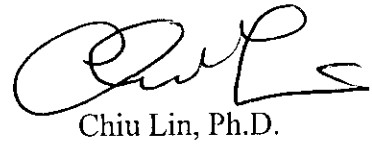
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number K041655

Applicant: Cowell Medi Company, Ltd.

Device Name BioPlant System

Indications for Use

BioPlant Systems refer to sets of root form endosseous dental implants and compatible implant abutment systems. BioPlant Systems are designed for use in dental implant surgery and are intended to be used in a manor in which they (the implants) integrate with the bone (osseointegration). The BioPlant abutment systems include various abutments designed to enable the implant process from healing thru final restoration. Clinical studies have demonstrated that, when surgically implanted under controlled conditions, a successfully osseointegrated implant will achieve a firm and direct connection between the living bone and surface of the titanium implant. BioPlant implants are for single or two-stage surgical procedures. Bio Plant Systems are intended for immediate placement in partially or fully edentulous mandibles and maxillae (type I or II bone), in support of single or multiple-unit restorations including; cemented retained, screw retained, or over-denture restorations, and terminal or intermediate abutment support for fixed bridgework. Multiple tooth applications may be splinted with a bar.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____X____ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041655